K122355

08/02/13

PREMARKET NOTIFICATION
510(k) SUMMARY OF SAFETY AND EFFECTIVENESS FOR VANISHPOINT® BLOOD COLLECTION SET
(21 CFR 807.92)

Applicant Name:	Retractable Technologies, Inc. 511 Lobo Lane Little Elm, TX 75068
Phone:	972-294-1010
Contact Person:	Rhonda Wells Regulatory Affairs Manager
Date of Summary Preparation:	January 23, 2013

AUG 2 3 2013

Trade Name:	VanishPoint® Blood Collection Set
Common Name:	Blood Collection Set
Classification Name:	Tubes, Vials, Systems, Serum Separators, Blood Collection
Device Classification:	Class II

Legally Marketed Substantially Equivalent Device:

K030573 – BD Vacutainer Push Button Blood Collection Set
K112512 - VanishPoint® Blood Collection Set

Description of Device:

The VanishPoint® Blood Collection Set is safety device that is sterile and non-pyrogenic and is designed for collection of blood specimens or intravenous administration of fluid. The device will initially be available with either 7" or 12" tubing, ¾" length needles and gauge sizes of 19, 21, 23 and 25.

Intended Use:

The intended use of the VanishPoint® Blood Collection Set is to provide safe and reliable access to the vascular system to obtain blood specimens from patients. The VanishPoint® Blood Collection Set is also indicated for intermittent or short-term intravenous administration of fluid (up to 2 hours). It may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.

The VanishPoint Blood Collection Set aids in the prevention of needlestick injuries.

The BD Vacutainer is indicated for both blood collection and intravenous administration of fluids. The VanishPoint® BCS was originally cleared for blood collection only.

Engineering Testing: The VanishPoint® Blood Collection Set was previously cleared as substantially equivalent to the BD Vacutainer Push Button Blood Collection Set with 510(k) K112512. For the purpose of this submission only testing pertaining to the additional indication will be provided. All other information can be referenced in the Predicate Device Section.

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Simulated Use Study: A simulated use study utilizing healthcare professionals was performed using the VanishPoint® Blood Collection set in a variety of uses. The subject device was found suitable for the intended uses and is as safe and effective and performs at least as safely and effectively as the legally marketed predicate device.

Comparison of Technical Characteristics:

The subject VanishPoint® Blood Collection Set and the BD Vacutainer predicate device are similar in design, technological characteristics and materials. The subject device that is the purpose of this 510(k) submission is identical to the previously cleared VanishPoint® BCS device. To support the addition of the new indication, an extractable study was performed with acceptable results. Biocompatability testing was performed under the previously cleared 510k submission. All three devices are labeled to obtain blood specimens from patients. The subject device and BD Vacutainer predicate device are also indicated for intravenous administration of fluid.

Substantial Equivalence: The operation, similar design and materials between the predicate devices and the subject device do not raise new issues of safety and effectiveness when used as labeled. The intended use of the predicate and subject devices is virtually identical. It is our opinion that the devices are substantially equivalent.

Conclusion: The purpose of this submission is to add an additional indication to allow intermittent or short-term intravenous administration of fluid. The addition of this indication does not affect any of the previously presented functional testing such as needle pullout force, trigger force, tubing connection strength, tubing strength, air, liquid leakage and complete needle retraction. A Simulated Use Study was performed to ensure the subject device is suitable for the additional indication. In addition Biocompatibility testing was performed and the Sterilization Validation was completed (SAL 10^{-6}) according to the applicable standards. The information included within this pre-market notification demonstrates that the VanishPoint® Blood Collection Set is substantially equivalent to the predicate devices for the intended usage.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 23, 2013

Retractable Technologies, Incorporated
Ms. Rhonda Wells
Regulatory Affairs Manager
511 Lobo Lane
LITTLE ELM TX 75608

Re: K122355
Trade/Device Name: VanishPoint® Blood Collection Set
Regulation Number: 21 CFR 862.1675
Regulation Name: Blood Specimen Collection Device
Regulatory Class: II
Product Code: JKA, FPA
Dated: August 20, 2013
Received: August 21, 2013

Dear Ms. Wells:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K122355

Device Name: VanishPoint® Blood Collection Set

Indications for Use:

The intended use of the VanishPoint® Blood Collection Set is to provide safe and reliable access to the vascular system to obtain blood specimens from patients.

The VanishPoint® Blood Collection Set is also indicated for intermittent or short-term intravenous administration of fluid (up to 2 hours). It may be used for any patient population with consideration given to adequacy of vascular anatomy and appropriateness of procedure.

The VanishPoint Blood Collection Set aids in the prevention of needlestick injuries.

Prescription Use √ AND/OR ____Over-The-Counter Use ____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Richard C. Chapman
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(Optional Format 3-10-98)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K122355